FILED ELECTRONICALLY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	: 10/659,930	Confirmation No. 5064
Applicant	: Wayne E. Cornish et al.	
Filed	: September 11, 2003	
Title	: GUIDEWIRE HAVING LINEAR CHANGE IN STIFFNESS	
Art Unit	: 3736	
Examiner	: Jonathan M. Foreman	
Docket No.:	: ACSG-65357 (G1298USC2)	
Customer No.	: 24201	May 3, 2010

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents

PRE-APPEAL BRIEF REQUEST FOR REVIEW

I. INTRODUCTION

The present invention is directed to an improved tapered guide wire providing enhanced distal support while having a flexible distal tip to provide acceptable steerability and little risk of damage to vessel or chamber linings when advanced through a patient's body lumen such as veins and arteries. For certain procedures, such as when delivering stents around challenging anatomy, e.g. a shepherd's crook, tortuosities or severe angulation, substantially more support and/or vessel straightening is frequently needed from the guide wire than normal guide wires can provide. Guide wires have been commercially introduced for such procedures which provide improved distal support over conventional guide wires, but such guide wires are not very steerable and in some instances are so stiff that they can damage vessel linings when advanced therethrough. In addition, conventional guide wires using tapered distal core sections can be difficult to use in many clinical circumstances because **they have an abrupt stiffness change along the length of the guide wire, particularly where the tapered portion begins and ends**. When a guide wire having a core with an abrupt change in stiffness is moved through tortuous vasculature of a patient, the physician moving the guide wire can feel the abrupt resistance as the stiffness change is deflected by the curvature of the patient's vasculature. The abrupt change in resistance felt by the physician can hinder the physician's ability to safely and controllably advance the guide wire through the vasculature.

The present invention provides a tapered guide wire that does not have an abrupt change in stiffness since the guide wire has been specially manufactured to have a substantially linear change in bending stiffness over its longitudinal length.

II. NOTICE OF APPEAL

A Notice of Appeal from the final Office Action dated February 3, 2010 is being filed concurrently herewith along with the appropriate fee.

III. ISSUES ON APPEAL

At issue is whether claims 64, 65, 67-76 and 78-83 were improperly rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,120,308 to Hess (the "Hess patent").

A copy of the pending claims is attached as Exhibit A. A copy of the drawings from the application is attached as Exhibit B. A copy of the final Office Action dated February 3, 2010 is attached as Exhibit C. A copy of the Hess patent is attached as Exhibit D.

IV. ARGUMENT

A. Rejection of the Claims Based on the Hess Patent

Appellant strongly disagrees with the Examiner's position regarding the disclosure of the Hess patent. The Examiner has basically taken the position that the tapered segments disclosed in the Hess patent must necessarily produce a substantial linear change in bending stiffness over the length of the member since the tapered sections have a substantially linearly reduced cross sectional and that bending stiffness is directly proportional to cross sectional area. However, the Examiner has provided no technical support for any of these statements and has fails to cite to any disclosure in the Hess patent which supports this position.

Appellant submits that a guide wire with tapered segments having a substantially linearly taper does not possess substantially linear change in bending stiffness over the length of that guide wire. The Hess patent discloses a guide wire with a constant taper angle which exhibits an abrupt change in stiffness at various points along the guide wire. The Hess guide wire exhibits the type of bending stiffness discussed at pages 28-29 and FIGS. 11 and 12 of the Specification. Appellant's presently claimed invention requires **substantial forming operations** to produce the **substantially linear change in bending stiffness over the entire longitudinal length of the elongated member.** As is addressed in the specification at page 8, the taper must be created through a grinding operation,

or other forming means such as chemical etching, or laser cutting. Appellant's relevant disclosure at page 8 reads as follows:

> Multiple tapers may be **ground** simultaneously or as separate operations. A centerless grinder with profile capabilities may be used to **grind the tapers** simultaneously. A manual centerless grinding may be employed to create separate tapers in separate operations. Tapers may also be formed by other means such as chemical means, e.g. **etching, or laser means**.

The Hess patent provides absolutely no disclosure that the tapers on the core of its disclosed guide wire are specially processed to achieve a structure having substantially linear change in bending stiffness over the entire longitudinal length of the elongated member. Rather, the Hess patent discloses the type of conventional guide wire which the present invention was designed to correct through the use of multiple tapers having a substantially linear change in bending stiffness. The Examiner merely relies on unsupported statements based on a belief that a substantially linear reduction in a tapered section would produce a substantially linear change in bending stiffness. Again, the Examiner has provided no support for this position.

The disclosure in the Hess patent does address the use of tapered section to form the guide wire but fails to provide any disclosure that the guide wire exhibits a linear change in stiffness along the length of the guide wire. The tapered sections of the guide wire in the Hess patent are described as follows at Column 7, line 65 to Column 8, line 3:

> FIG. 1 shows the detailed structure of the guide wire 14 wherein the guide wire is non-uniform in cross-section. Specifically, guide wire 14 preferably comprises a plurality of tapered sections 16, 18 and 20. Although three sections are shown, it is understood that any number of sections and/or a continuous taper are within the scope of the invention.

There is no mention in the Hess patent with respect to these tapered sections 16, 18 and 20 that these tapered segments are **configured to produce** a substantially linear change in bending stiffness over the length of the guide wire. Tapered segments are also addressed with respect to an embodiment disclosed in FIG 8. Here, the Hess patent states the following at Column 9, lines 60-66:

> The high flexibility of the extension wire, which preferably has a plurality of tapered sections 50, 52 and 54, provides variable strength along the length thereof from greater to lesser strength extending away from the distal end of the hollow body portion 46 to provide trackability, pushability and flexibility of the guide wire.

Again, there is no mention in this passage that these tapered sections 16, 18 and 20 are configured to produce the substantially linear change in bending stiffness over the length of the guide wire. While these tapered sections in the Hess patent may be flexible, there is no indication

that they are achieve a substantially linear change in bending stiffness over the length of the guide wire.

The Hess patent also states the following at Column 6, lines 63-69:

> In the nickel-titanium alloys of the present invention f varies as E does not apply once bending has been initiated, as can be seen in FIG. 2. Once bending is initiated, very little additional stress is required to continue the bend. Also, since the mechanism is stress-induced martensite which occurs only "locally" in the region stressed, a non-uniform deflection can occur without the requirement of a uniform radius.

This language appearing in the Hess patent is descriptive of a phenomenon of stress induced martesite in a shape memory alloy. The present claims are not directed to this phenomenon. Appellant submits that the Hess patent simply does not disclose of suggest an elongated member having linear change in stiffness.

Appellant respectfully notes that the Examiner must prove a prima facia case of anticipation in order to properly reject claims. There is no support for the Examiner's statements regarding guide wire geometry and bending stiffness and no disclosure found in the Hess patent to support the Examiner's position. Accordingly, the Examiner has failed to establish a prima facia case of anticipation. Anticipation cannot be proven by conjecture or speculation. For these reasons, the Hess patent should be withdrawn as an anticipatory reference and the pending claims should be allowed to issue.

Appellant refers to the present Specification, particularly, Figures 11 and 12 (Exhibit B), which shows the characteristics of a conventional tapered guide wire. The bending stiffness plot of Figure 12 shows how the tapered portion of a conventional guide wire **does not exhibit** a substantially linear change in bending stiffness. The plot between points B and C which shows the characteristics of the tapered portion of the guide wire. In this region, the bending stiffness is quite steep and curved. This graph should be compared with the graphs of Figures 13 and 14 (Exhibit B) which shows that the tapered portion of a guide wire made in accordance with the present invention achieves a substantially linear change in stiffness between point B and C.

Claim 71 recites a guidewire comprising an elongate core member with at least one longitudinal section having a tapering diameter and a substantially linear change in bending stiffness over a longitudinal length thereof and defined substantially by the formula:

$$D_L = \left[\frac{64CL}{E\pi} + D_o^4 \right]^{\frac{1}{4}}$$

Where D_L is the diameter of the elongate core member at length L from a position of starting diameter D_o, L is a length greater than zero, E is the modulus of elasticity of the core member material, and C is a constant that depends on the boundary conditions of the longitudinal section.

Claim 78 defines a guidewire comprising an elongate core member with at least one longitudinal section having a substantially linear change in bending stiffness over a longitudinal length thereof and a moment of inertia defined substantially by the formula:

$$I_L = \frac{CL}{E} + I_o$$

Where I_L is the moment of inertia of the longitudinal section at length L from a position of starting inertia I_o, L is a length greater than zero, E is the modulus of elasticity of the longitudinal section, and C is a constant that depends on the boundary conditions of the longitudinal section.

The Examiner acknowledges that the Hess patent does not expressly disclose the formulas set forth in claims 71 and 78, but has taken the position that the guide wire of the Hess patent is sufficient to read on these claims. However, as expressed above, the Examiner fails to identify any disclosure in the Hess patent which states that the guide wire has at least one longitudinal section having a tapering diameter with a substantially linear change in bending stiffness over a longitudinal length thereof.

V. CONCLUSION

The Examiner's finding of anticipation based on the Hess patent is based on unsupported statements and disclosure. Appellant respectfully requests that the anticipation rejections based on the Hess patent be withdrawn.

The Commissioner is hereby authorized, however, to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 06-2425.

Respectfully submitted,

FULWIDER PATTON LLP

/Thomas H. Majcher/
Thomas H. Majcher, Reg. No. 31,119